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Date 10-27-08

By Angela Loding
Angela Loding

PATENT
Attorney Docket No.: PX-15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Yves P. Arramon

Application Serial No.: 10/723,248

Filing Date: November 25, 2003

Title: REMOTELY ACTUATED SYSTEM FOR BONE CEMENT DELIVERY

Examiner: Cumberledge, Jerry L.

Group Art Unit: 3733

Confirmation No.: 6049

DECLARATION PURSUANT TO 37 CFR §1.131

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, the undersigned, hereby declare and state that:

1. I am over the age of 21 years, of sound mind, and competent in all respects to make this Declaration.

2. I am an employee of ArthroCare Corporation, the current assignee of record for the above-referenced non-provisional patent application, entitled *Remotely Actuated System for Bone Cement Delivery*, filed on November 25, 2003, ("the Application"). Thus, the Application claims the priority date of November 25, 2003.

3. Prior to my employment with ArthroCare, I was an employee of Parallax Medical Inc., which was acquired by ArthroCare on January 29, 2004, and which was the assignee of record for the Application at the time of filing.

4. During my employment with Parallax Medical and ArthroCare, I had knowledge of and was familiar with the work performed on the subject of the Application by Yves Arramon, the sole inventor of the subject matter of the Application.

5. The Examiner rejected Claims 25, 26, 32 and 34 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0070915 by Michael Mazzuca et al. ("Mazzuca"), filed on September 22, 2004.

6. The Examiner rejected Claims 27-31 and 33 under 35 U.S.C. § 103(a) as being unpatentable over Mazzuca alone or in combination with other cited references.

7. The present invention was conceived and reduced to practice in the United States prior to September 26, 2003, the effective date of the cited Mazzuca Reference.

6. Such conception and reduction to practice is evidenced by the following attached exhibits--Exhibit A: Engineering Notebook entry of December 4, 2001, signed by inventor Yves Arramon; Exhibit B: Engineering Notebook entry of May 20, 2002, signed by inventor Yves Arramon and myself as read and understood on February 11, 2003; Exhibit C: Invention Disclosure Form, attached hereto, and signed by inventor Yves Arramon and two witnesses, George Delli-Santi and Michael Denker, on July 24, 2002; Exhibit D: Engineering Notebook entry of August 30, 2002, signed by inventor Yves Arramon and myself as read and understood on February 11, 2003; and Exhibit E: Engineering Notebook entry of September 3, 2002, signed by inventor Yves Arramon and myself as read and understood on February 11, 2003.

7. In approximately late August of 2002, a prototype device, consistent with the designs described in the attached Exhibits was constructed.

8. In approximately early October of 2002, testing was performed on a prototype device consistent with the designs described in the Application and the attached Exhibits.

9. The present invention described in the Application was actually reduced to practice in a prototype device constructed and tested on or before October 8, 2002.

10. Such actual reduction to practice and prototype testing is evidenced by the following attached exhibits—Exhibit F: Engineering Notebook entry of October 8, 2002, signed by inventor Yves Arramon and myself as read and understood on February 11, 2003.

All statements made herein of my/own knowledge are true, all statements made herein on information and believe are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

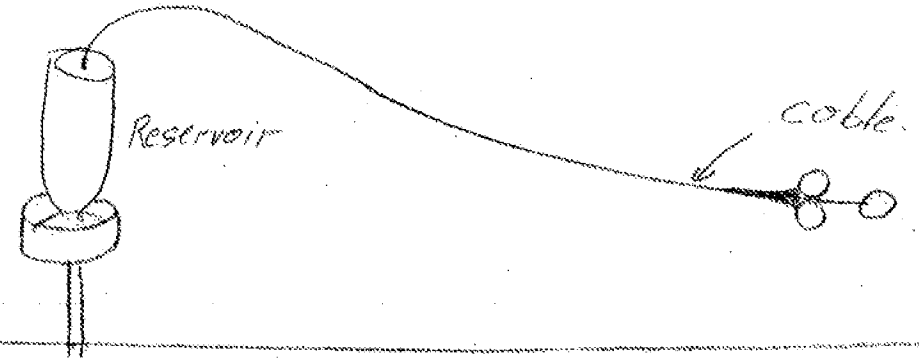
Scott McIntyre

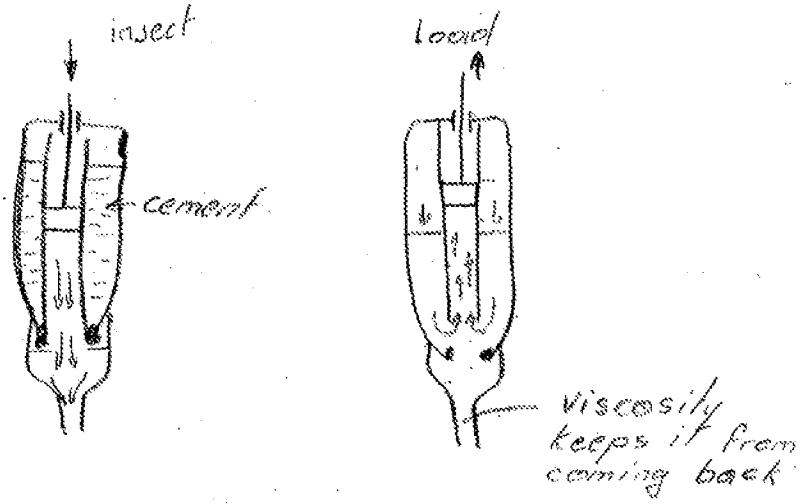
SCOTT MCINTYRE

Date: 23 OCT 08

Nov 01

New Cement Injection Device





Thur 11/04/01

Advantages: - low device stress. ← Important
- More direct control of flow.
- Control and actuation of the flow can be accomplished from further away from the field and in a more comfortable position
- less leftover cement (no long connecting tube)

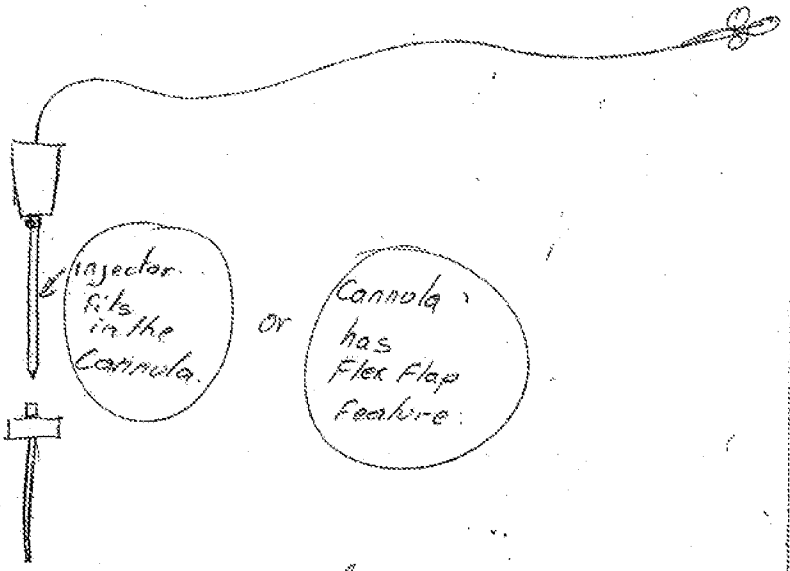
Disadvantages: - Needle becomes top heavy
- more parts to fail
- You can only draw back as much cement as the plunger will accept

Jon Thurn

EXHIBIT A
Application No. 10/723,248
Engineering notebook entry of 12-4-01

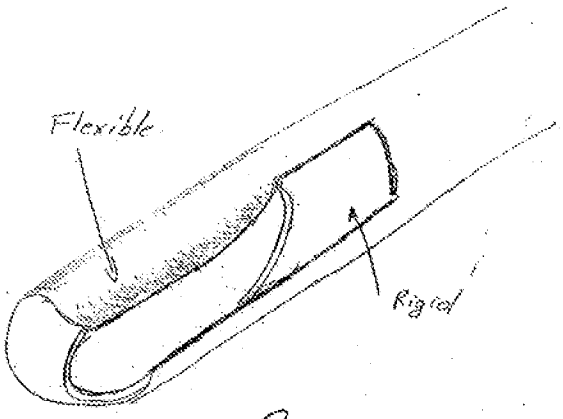
New Injection System 05/20/02

This system is an extrapolation of the "Remotely actuated pump". In this case the pumping occurs in the cannula



Yhs 05/20/02

The pumping is accomplished by means of a "Flex Flap" feature.



Yhs 05/20/02

PARALLAX MEDICAL, INC. (PMI)

INVENTION DISCLOSURE FORM

1. **Title of Invention:** ___**Percutaneous Viscous Fluid Delivery Device** _____

2. **Proposed Contributors to Invention.**

Contributor #1 __Yves P Arramon____ Contribution _Concept and design _____

_____

Contributor #2 _____ Contribution _____

_____

Contributor#3 _____ Contribution _____

_____

3. **Summary of the Invention.** A system for the delivery highly viscous fluids or pastes or bone cement employing a remotely actuated cement pump.

4. **Background of the Invention.** Most percutaneous injection devices used for the percutaneous delivery of viscous fluids and pastes such as bone cement are variations of a "large syringe" design. The fluid is pressurized within the syringe body by means of a plunger. The pressurized fluid is conveyed to a needle by means of a tube that is often flexible. For highly viscous fluids, the backpressures required to push the fluid along are unusually high. When, in addition, this fluid is compressible the user of the device can perceive a time lag between the actuation of the device and the fluid delivery responses. This reduces the usefulness of the device when precise volume control is important. An alternative method, which obviates the control issue, is to use a small volume syringe directly connected to the needle or in the extreme case to use a plunger within the needle itself. One of the disadvantages to this approach is that the device usually contains an insufficient amount of fluid and must be discarded when emptied. Furthermore, if the device is used in conjunction with a radiative imaging device such as a fluoroscope or CT or PET scanners, the user must extend their hands close to the patient and the radiation field. The approach described in this submission (Figure 1) combines the best qualities of both the large syringe with a connecting tube and the small syringe connected directly to the needle. By bringing the pressurization close to the delivery site with a small pumping volume the working pressures are lowered and the responsiveness of the device is improved. By providing a remote actuation (as is the case with large syringe and connecting tube) the users is in a safer more comfortable position out of the field of radiation and closer to the user body. By providing a continuously reloadable pumping mechanism the amount of fluid available to inject is not limited to the small pumping volume.

5. **Detailed Description of the Invention.** The device consists of a remotely actuate pump. In this case the pump is a small volume syringe, the actuating element is flexible control cable (figure 2). The actuation is manual and controlled by the physician. e 2). By sliding the tubes and elastic elements with respect to each other, the device will bend in a controlled manner

and at predetermined locations along the device. The catheter tube may be constructed with different features so as to provide a multitude of functionalities (figure 3).

6. **Relevant Dates**

   a. **First date on which Invention was Conceived and/or demonstrated/tested.**

      (a) First conceived 12/04/01 (Lab notebook entry Arramon2 page 9) Parallax Medical (Scotts Valley, CA).

   b. **First date of disclosure of Invention within PMI.** First disclosed on 12/14/01, Parallax Medical Inc. (Scotts Valley, CA) during a brainstorm meeting for a new Cement Delivery System.

7. **Related Government or Other Contract Information.**
   None.

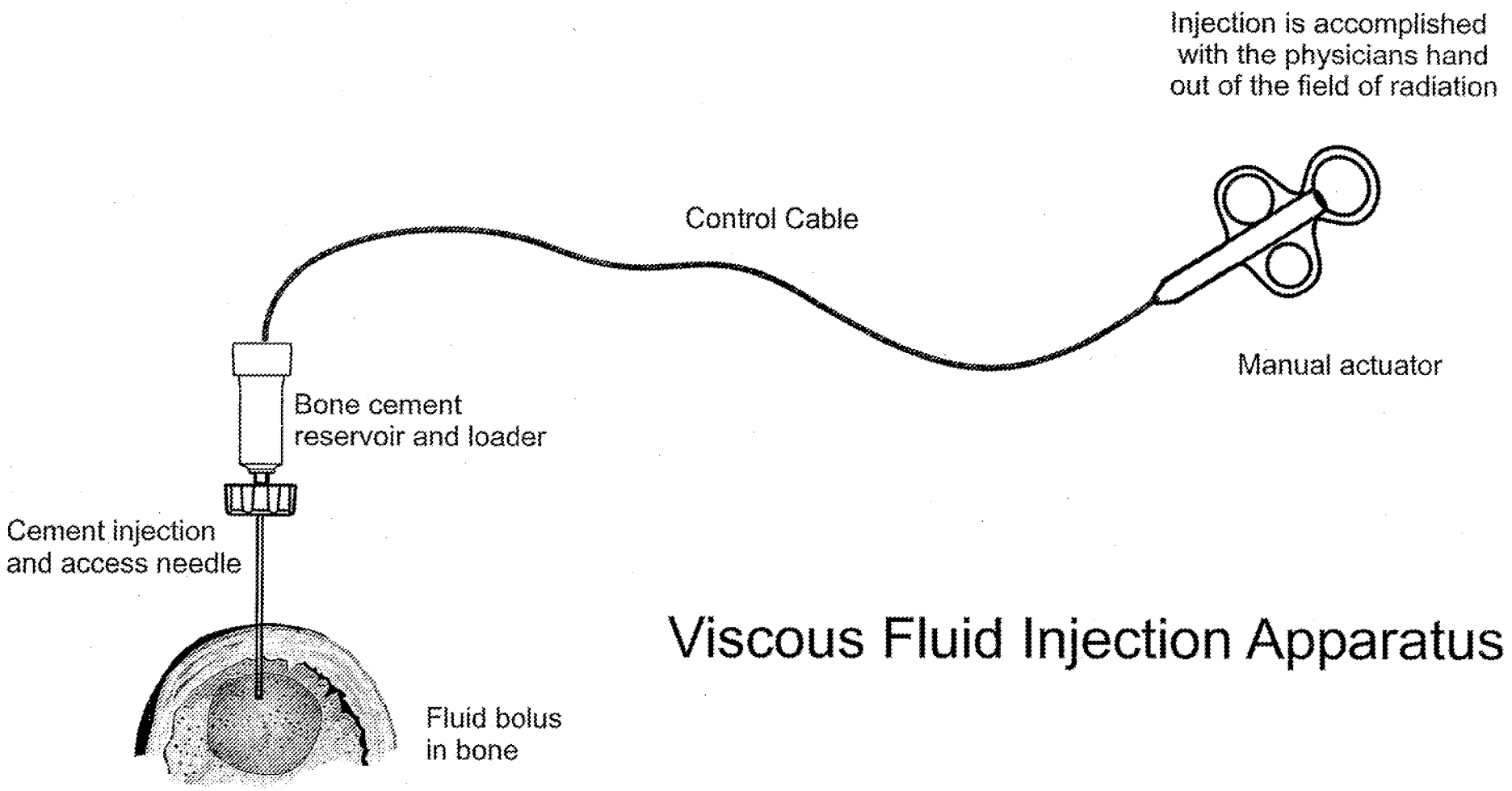
8. **Contributors**

(1)	Yves P Arramon (Name)	(Signature)	07/24/02 (Date)
(2)	(Name)	(Signature)	(Date)
(3)	(Name)	(Signature)	(Date)

9. **Witnesses**
   (Witnesses must understand the significant details of the invention and must appreciate the factors which enable successful functioning of the invention for its intended purpose. A co-inventor cannot be a witness).

   Witness Statement:
   I have read and understand this Invention Disclosure.

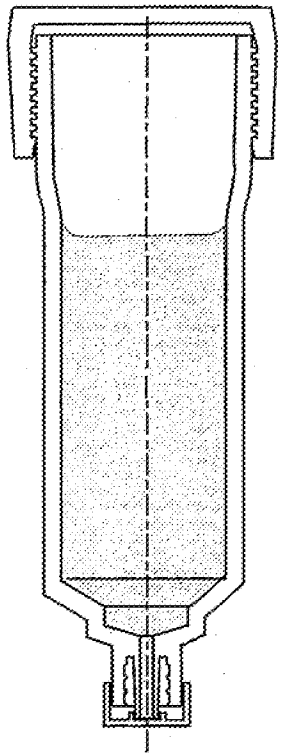
(1)	George Delli-Santi (Name)	(Signature)	7-24-02 (Date)
(2)	Michael Denker (Name)	(Signature)	7/24/02 (Date)



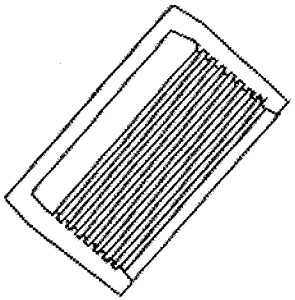
Viscous Fluid Injection Apparatus

EXHIBIT C
Application No. 10/723,248
Invention Disclosure Form

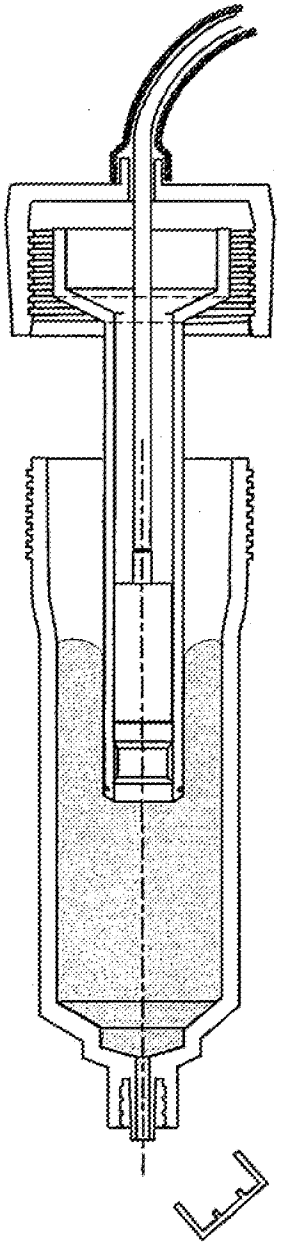
The reservoir may be used for mixing



Cap is removed



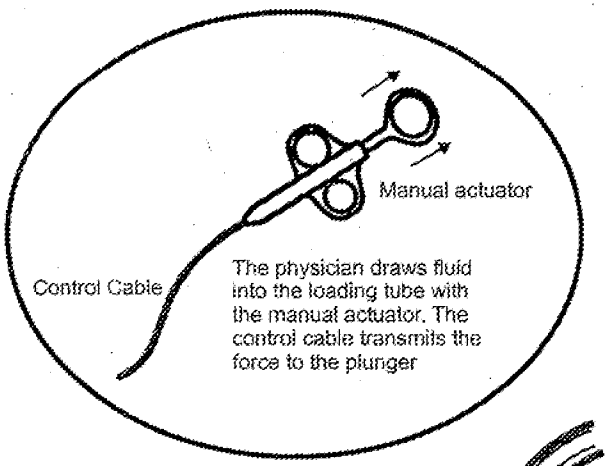
And

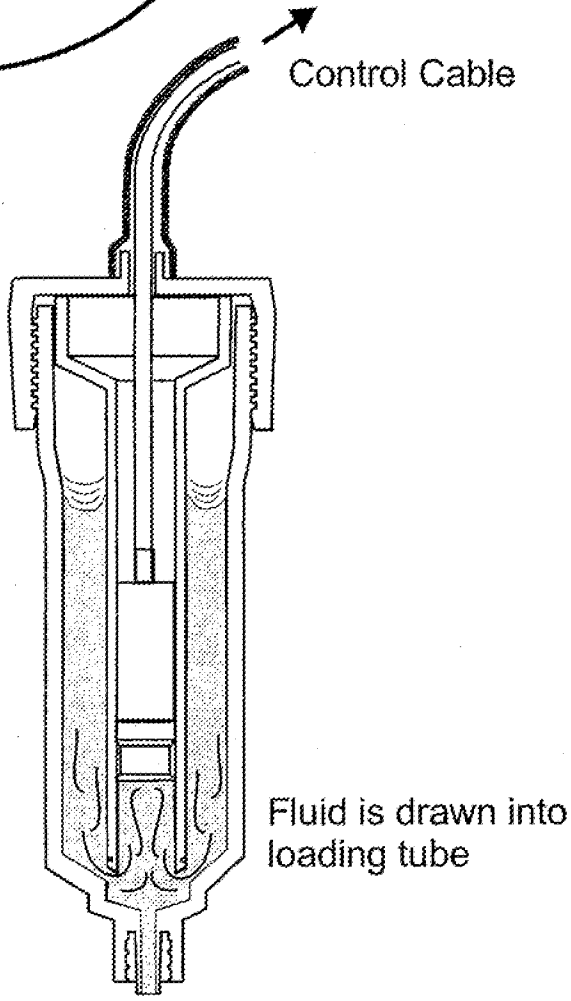


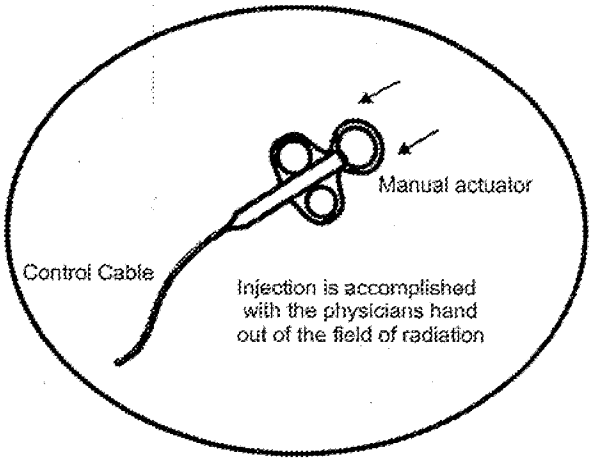
Replaced with the remote pump assembly

Then plug is removed and the device is connected needle

EXHIBIT C
Application No. 10/723,248
Invention Disclosure Form







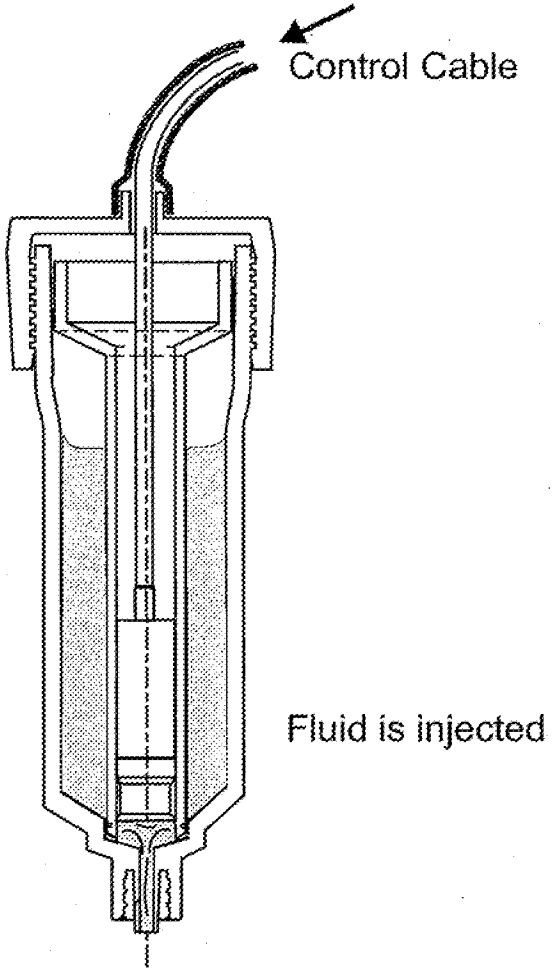
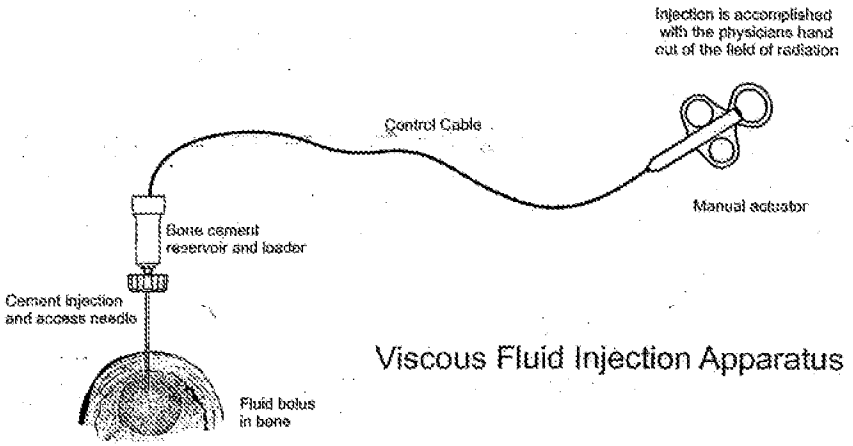


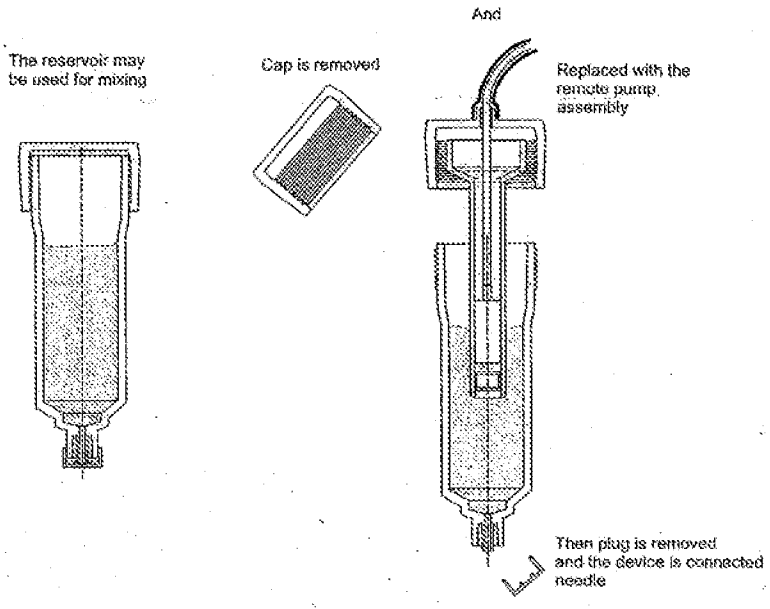
EXHIBIT C
Application No. 10/723,248
Invention Disclosure Form

– More on the New Injection System – 08/29/02



Viscous Fluid Injection Apparatus

Chris Hayes 08/30/02



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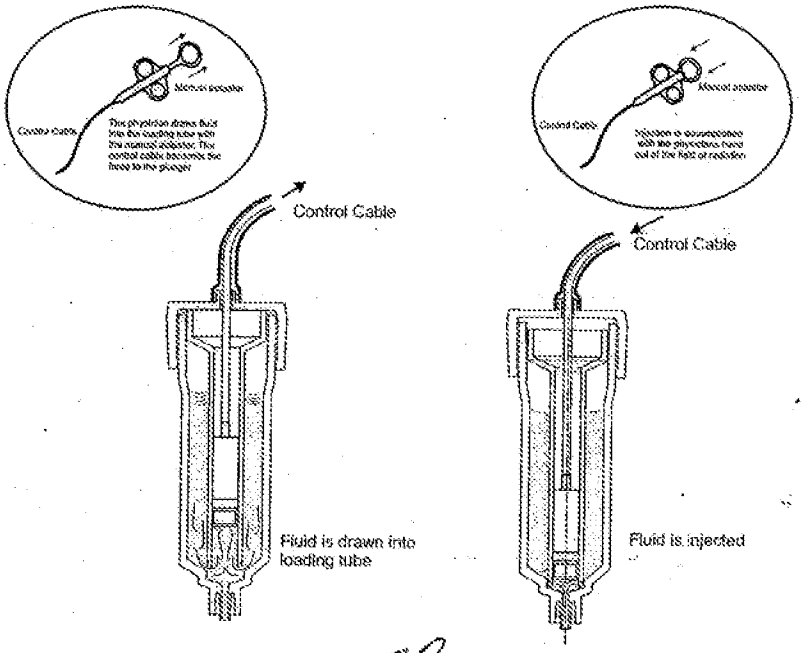
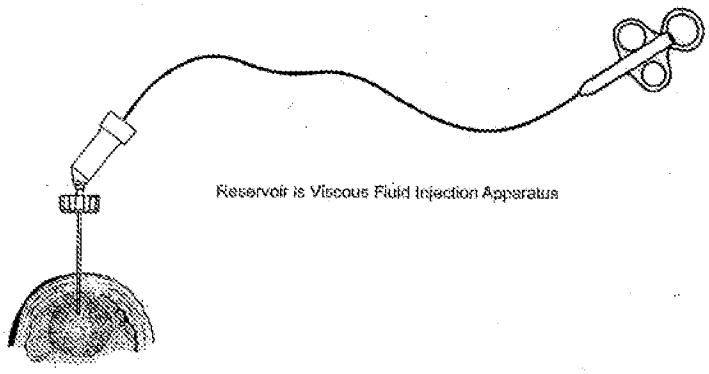
New Injection System



08/29/02

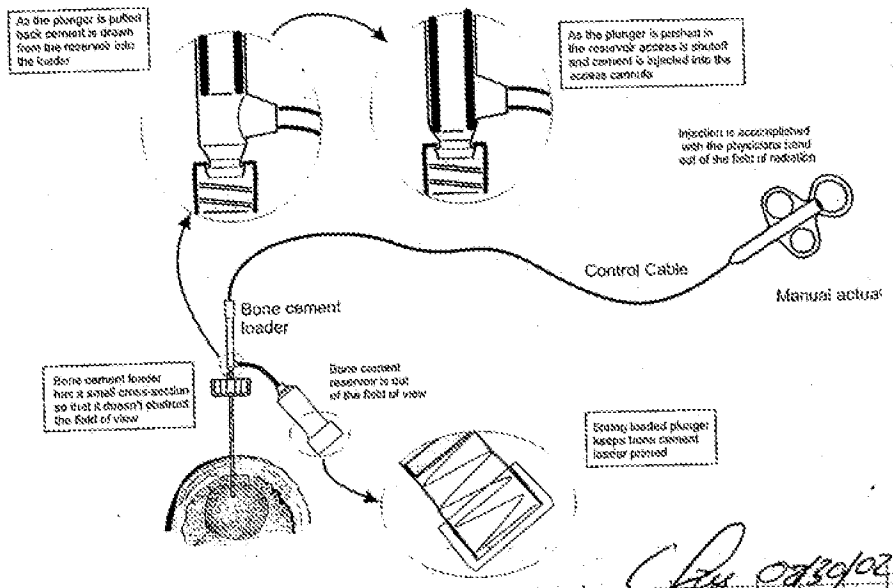
Variation A: Viscous Fluid Injection Apparatus



08/30/02

New Injection System

Variation B: Viscous Fluid Injection Apparatus



Jeu 03/30/02

Variation C: Viscous Fluid Injection Apparatus

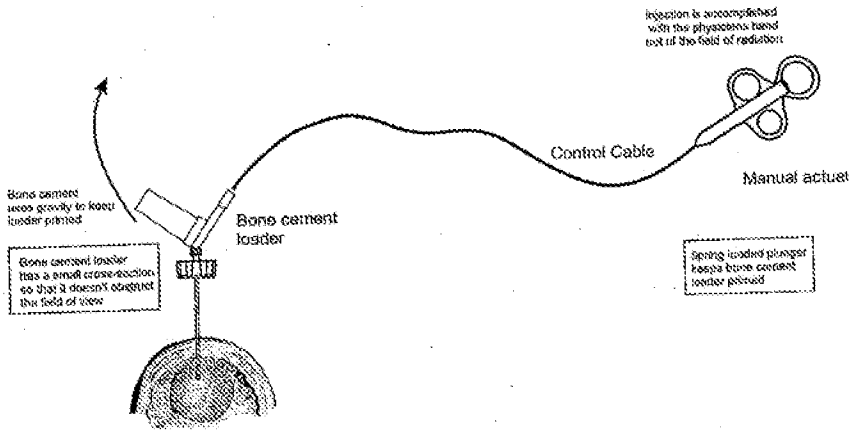


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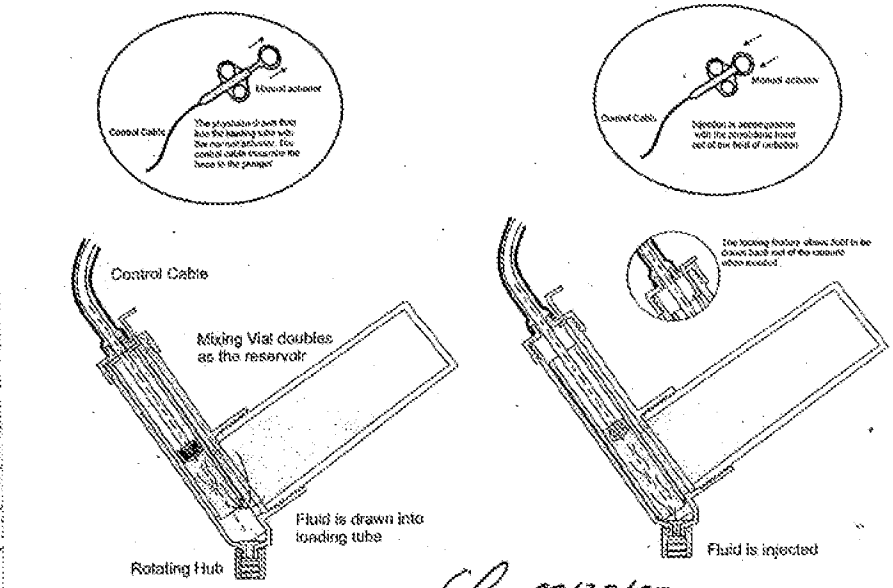
EXHIBIT D
Application No. 10/723,248
Engineering Notebook entry of 8-30-02

18 [ARR2]

New Injection System

08/30/02



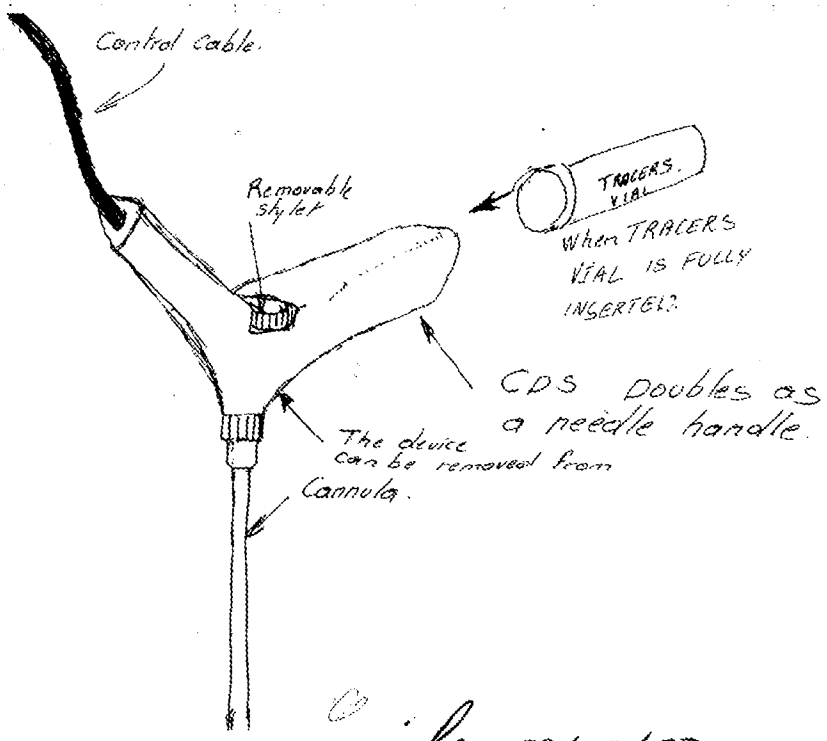
08/30/02

08/30/02

Read + Understood
S.M. Intag
2/11/03

[End]

03/03/02 More Variation of the New Injection System



03/03/02

Characteristics:

- The CDS doubles as a needle handle.
- The CDS can be removed from the cannula (more clearance).
- Vial is perforated when fully inserted (reduced time exposure).
- Remotely actuated delivery (reduced radiation exposure)

- Control cable (linear response)

EXHIBIT E
Application No. 10/723,248
Engineering notebook entry of 9-3-2002

Read + Understood: Scott Mehta 2/11/03

Oct 8th 2002 VFIS prototype.

see Tape. (VFIS Tape #1 Experiment #1)

- Viscosity prevents honey from flowing easily into the loading area
- Puncture on the back of the vial allowed honey to flow.
- loose luer tends to allow air bubbles to be drawn in to the chamber
- Single action plunger may allow air to seep into the loading chamber
- Mixing one full demo Trocers int

Read + Understood.

Scott McIntyre 2/11/03

Jay Thomas at 7th 2002

EXHIBIT F
Application No. 10/723,248
Engineering notebook entry of 10-8-02